



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy
239 Causeway Street, Suite 200, 2nd Floor
Boston, MA 02114
(800) 414-0168 (office) / 617-973-0983 (fax)
<http://www.mass.gov/reg/boards/ph>

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COMMISSIONER

JEAN K. PONTIKAS
DIRECTOR

**APPLICATION FOR REGISTRATION TO MANAGE AND OPERATE
A NEW COMMUNITY PHARMACY**

(1) In order to be registered by the Board to manage and operate a pharmacy or pharmacy department and be issued a permit to do so, the registered pharmacist who shall be responsible for the management and operation of the pharmacy or pharmacy department shall obtain and submit to the Board an application for registration to manage and operate a pharmacy or pharmacy department available from the Board. A completed application shall be:

(a) fully and properly completed and signed, under the penalties of perjury, by the pharmacist who is to manage and operate the pharmacy or pharmacy department;

(b) accompanied by a statement of the scheduled hours during which the pharmacy or pharmacy department is to remain open, including the time of opening and closing during regular business hours for each day of the week;

(c) accompanied by an application, available from the Board, for a Massachusetts controlled substance registration;

(d) accompanied by an application, available from the Board, for a certificate of fitness, if applicable;

(e) accompanied by a check or money order made payable, in the proper amount, to the "Commonwealth of Massachusetts Board of Registration in Pharmacy"; and

(f) accompanied by any additional information as determined by the Board.

(g) accompanied by an official blueprint or certified architectural plans drawn to scale clearly designating both the prescription and patient consultation areas (pharmacy department shall be outlined in RED).

(2) A completed application to operate a pharmacy shall include:

(a) a copy of the corporation's Articles of Organization, signed and sealed by the Secretary of State if the corporation is incorporated in the Commonwealth;

(b) a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of State pursuant to M.G.L. c. 181, § 4, if the corporation is incorporated in another state;

(c) a statement of the name and address of each officer and director of the corporation and the position held;

(d) the d/b/a name of the corporation; and

(f) if the corporation is not publicly owned, the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s).

(3) The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges.

(4) Before acting upon any application for registration to manage and operate a pharmacy or pharmacy department, the Board may require a hearing and, if requested to do so, the applicant shall personally appear before the Board to answer questions to enable the Board to determine that issuance of a permit would be in the best interests of the public health, welfare and safety as set forth in M.G.L. c. 112, § 39.

(5) The Board may require an inspection of the pharmacy or pharmacy department before final approval of the application is granted. All proposed pharmacies and pharmacy departments shall comply with the following requirements:

(a) No application for registration to manage and operate a pharmacy or pharmacy department shall be approved unless, upon inspection, the following is maintained on the pharmacy premises:

1. a current copy or electronic version of the Massachusetts List of Interchangeable Drugs (MLID), including the Orange Book, Additional List, Exception List, and the latest supplements thereto;

2. a current copy or electronic version (with quarterly updates) of a compendia appropriate to the practice setting approved by the pharmacist manager of record.

3. a current copy or electronic version of Board Regulations 247 CMR 1.00 et seq.;

4. a balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually;

5. the equipment necessary to conduct the practice of pharmacy according to the standards set forth by most current edition of the United States Pharmacopoeia;

6. prescription labels which bear the name and address of the proposed pharmacy;

7. appropriate sanitary appliances, including a suitable sink which shall be equipped for hot and cold running water and which shall be situated in or near the area in which prescriptions are to be filled;

8. whenever applicable, at least one bound book for recording sales of controlled substances which may be sold over-the-counter without a prescription; and

9. whenever applicable, at least one book for recording sales of alcoholic beverages and signatures of the purchasers of these beverages.

(b) There shall be within every pharmacy or pharmacy department a prescription area of not less than 300 square feet to accommodate the appropriate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation and compounding of prescribed medications. This area shall provide for an arrangement and storage of drugs that is calculated to prevent their accidental misuse.

(c) Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) shall, in addition to the 300 square feet required by 247 CMR 6.01(6)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. This clean room shall meet the following requirements:

1. There shall be a minimum working area of 72 square feet;
2. it shall be closed on all sides except for a door and an opening to allow for the passage of materials;
3. it shall have a laminar flow hood with either vertical or horizontal air flow;
4. the laminar flow hood standards of operation of HEPA (High Energy Particulate Air) filters and prefilters must be determined and certification shall be made annually by a Board-approved hood certification service;
5. the Board shall be notified before beginning operation of the clean room to verify hood certification;
6. the area of the clean room shall be under continual positive pressure unless the hood is self-venting; and
7. applications for construction of a pharmacy with a clean room received after September 30, 1996 shall show the clean room located directly adjacent to the prescription area/department.

(d) Patient Consultation Area.

1. A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area.

2. 247 CMR 6.01(5)(d) shall be effective for all new or relocating pharmacies on April 1, 2005. All existing pharmacies must comply with 247 CMR 6.01(5)(d) by January 1, 2007.

(6) The Board shall issue a permit indicating the pharmacy or pharmacy department's registration number if the Board finds, in its reasonable discretion, that approving the application would be consistent with the best interest of public health, welfare and safety.

(7) All fees submitted to the Board in connection with an application for registration to operate a pharmacy or pharmacy department, which are reviewed and acted upon by the Board, are nonrefundable.

Please be advised that no pharmacy and pharmacy department shall begin to operate until the application has been approved by the Board and: 1) the pharmacist Manager of Record has received from the Board a permit number to manage and operate the pharmacy and or pharmacy department, and 2) has received a controlled substances registration number.

For complete information regarding relocation regulations, please refer to 247 CMR 6.01 & 6.02. If additional information is necessary, please contact the Board office at (800) 414-0168.

To obtain a DEA number, please contact the Drug Enforcement Administration (DEA) office for an application. The address is: J.F.K. Federal Building

Drug Enforcement Administration
Room E400
15 New Sudbury Court
Boston, MA 02203-0131
(617) 557-2200



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APPLICATION FOR A NEW STORE

I hereby apply for a permit to operate a store for the transaction of retail drug business in accordance with the provisions of Chapter 112, General Laws.

\$351.00 licensure / application fee. Make check or money order for **\$351.00** payable to the Commonwealth of Massachusetts. **This fee is non-refundable.**

1. Legal Name of Business. _____
2. Full Business Address (Street Address, City, State and Zip). _____

3. Area Code and Telephone Number. _____
4. All trade or business names ("D.B.A." names) used by same Corporation or by License. _____

5. Type of ownership or operation (i.e., sole proprietorship, partnership, corporation). _____

If corporation, please submit articles of corporation.

5. Names(s) and Social Security Number(s) of the owner(s) and/or operator(s) of the licensee. *Please indicate type of ownership - Partnerships: the name of each partner and name address of partnership; Corporations: the name and title of each corporate officer and director, the corporate names, name and address of parent company, if any, and the State of incorporation; Sole Proprietorship: the name of the sole proprietor and the address of the business entity.*_____
- _____
- _____
7. Name of registered pharmacist charged with the management of the pharmacy._____
8. Registration number of above manager._____
9. Name(s) and registration number(s) of staff pharmacist(s) employed at pharmacy._____
- _____
- _____
10. Have any of the applicant(s) and/or managers-in-charge had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or other sanction(s) by federal, state or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution, or dispensing of any drugs, including controlled substances? Have any applications for licensure been denied by any federal or state agency including any state board of pharmacy? List and explain. Attach additional sheets if necessary.
- _____
- _____
11. The applicant/licensee must notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).
12. Social Security Number (**Mandatory**)._____
- Pursuant to M.G.L. c. 62C, s. 47A, the Division of Registration is required to obtain your social security number and forward it to the Department of Revenue. The Department of Revenue will use your social security number to ascertain whether you are in compliance with the tax laws of the Commonwealth.
13. List any licenses/certifications you hold in the United States or any country or foreign jurisdiction and the state/jurisdiction from which the license/certification was originally issued. Please attach a certificate of standing from each state or jurisdiction in which you are licensed/certified, indicating the status of your license and any relevant disciplinary information._____
- _____
- _____
14. Has any disciplinary action been taken against you by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: ☐ No: ☐
- If yes, please state the details (use a separate sheet if necessary)._____
- _____
- _____
15. Are you the subject of pending disciplinary actions by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes: ☐ No: ☐
- If yes, please state the details (use a separate sheet if necessary)._____
- _____
- _____

16. Have you ever voluntarily surrendered or resigned a professional license to a licensing/certification board in the United States or any country or foreign jurisdiction? Yes: ☐ No: ☐
If yes, please state the details (use a separate sheet if necessary)._____

17. Have you ever applied for and been denied a professional license in the United States or any country or foreign jurisdiction? Yes: ☐ No: ☐
If yes, please state the details (use a separate sheet if necessary)._____

18. Pursuant to Board Regulations at 247CMR § 6.01(3), **The Board shall not register nor permit ownership of a pharmacy or pharmacy department by a practitioner with prescriptive privileges.** By signing this application the applicant certifies that none of the owners, directors or officers have prescriptive privileges.

Affidavit (must be completed and notarized)

Pursuant to M.G.L. c. 62C, s. 49A, I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

The applicant certifies that each person employed in any prescription drug distribution activity has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

I hereby state that I am the person authorized to sign this application for all licensure; that all statements are true and correct in all respects and are made under the penalties of perjury.

Signature of pharmacist who is to manage the pharmacy or pharmacy department

Date

Social Security Number of the Manager of Record

Sworn and subscribed before me this _____ day of _____

My commission expires _____ . _____

Notary Public

To be completed by the Board: Check \$ _____ Date _____ Number _____